

c)] a distal guidewire [port] opening in the distal end of the shaft;

[d)c) a proximal guidewire [port] opening spaced a relatively short distance of at least about 10 cm proximally from the [dilatation balloon] distal end of the shaft and a relatively long distance from the proximal end of the shaft; [and]

D5
d) a dilatation balloon on the distal shaft section having an interior in fluid communication with the inflation lumen and being space closer to the distal end of the shaft than the proximal guidewire port;

e) a guidewire passageway [at least 10 cm in length] which extends between the distal guidewire port and the proximal guidewire port and which is configured to slidably receive a guidewire therein.

REMARKS

Applicant's counsel wishes to thank the Examiner for the courtesies extended during the personal interview held on May 9, 1995.

The applicant also wishes to acknowledge with appreciation the Examiner's indication of the allowability of claims 18, 23, 25, 27 and 29. The above amendments to these claims are believed to overcome their rejection under 35 U.S.C. §112 (second paragraph).

The Examiner should note that minor changes were made to the above claims over those considered in the interview. Specifically, in claim 23, line 12, instead of deleting "therein" the expression "extending therein" was deleted. Also, as discussed during the interview, the product claims have amended to call for the identification of the patient to a human patient.

Claims 30-32 and 35 were rejected under 35 U.S.C. §102(b) as anticipated by Uthmann or in the alternative as being unpatentable under 35 U.S.C. §103 as being obvious over Uthmann. As to the rejection of claims 30-32, the applicant wishes to note that these claims require a guidewire with a core member and a coil on a distal portion of the core member. Uthmann describes advancing a catheter over a catheter, not a guidewire and particularly not a guidewire having a core member with a coil on its distal extremity. Member 11 of the Uthmann assembly is identified as a catheter with the function of returning blood to the same vein from which it was taken. To replace catheter 11 of Uthmann with a guidewire, as seemingly suggested by the Examiner in the rejection, would preclude return of blood to the same vein and would require a venous puncture for another blood return catheter, which was the very problem Uthmann sought to solve. Thus, Uthmann can neither anticipate nor render obvious claims 30-32. Claim 35, also rejected based upon the Uthmann reference, requires the proximal guidewire opening to be at least 10 cm from the distal end of the

a guidewire. Importantly, member 1 does not have a core member or a coil on a distal portion thereof. As in Uthmann *et al.* device, if catheter 1 of Weigl *et al.* is replaced with a conventional guidewire, it would not function as claimed and thus cannot be said to suggest the device as proposed by the Examiner.

The Examiner has also rejected claims 30-32 and 35 under §102(b) as being anticipated by Gants or, in the alternative, as being unpatentable under 35 U.S.C. §103 over Gants. In this rejection, the Examiner has alleged that the Gants catheter is inherently capable of being used in a patient's vasculature or that it is obvious to use the catheter in this manner. The applicant objects to rejection because there has been no reference by the Examiner to anything in this patent which would support the allegation of inherency. The only references regarding the use of the Gants catheter is found in column 2, lines 26-34 and column 3, lines 7-40 of this reference and in both instances it is negative in this regard because the device which slides over the intraluminal device is specifically precluded from entry into the body lumen of the patient. As indicated therein, the front surface 34 of balloon 28 is described as being large and flat to prevent entry of the balloon into the patient's urethra. As shown in Fig. 1, the balloon 28 has a flat front surface even in the non-inflated condition. The rejected claims 30-32 and 35 of the present application call for a means to perform

catheter and a substantial distance from the proximal end of the catheter shaft. There is no teaching in Uthmann in this regard. As indicated in Fig. 8 of Uthmann, the proximal port of catheter 12 of the Uthmann device is designed to be located outside of the patient during the procedure, which is contrary to the present invention, where the proximal guidewire port is designed to be within the patient during the procedure.

Claims 26, 28 and 30-36 stand rejected under 35 U.S.C. §103 as being unpatentable over Weikl *et al.*. Applicant has reviewed this reference in detail and believes that it does not suggest the invention claimed in these rejected claims as proposed by the Examiner. Claims 26, 28 and 30-36 all require the balloon or other means to perform the procedure to be spaced closer to the distal end of the catheter shaft than the proximal guidewire port. Weikl *et al.* on the other hand describes the balloon as being equi-distant from both ports. Additionally, claims 26, 30, 34 and 35 require the proximal port to be at least 10 cm from the distal end of the catheter shaft and there is no suggestion in Weikl *et al.* in this regard. Furthermore, claims 30, 32 and 33 call for a guidewire having a core member and a coil on a distal portion of the guidewire, whereas Weikl *et al.* does not suggest a guidewire, particularly a guidewire with a core and a coil on a distal portion of the guidewire. Member 1 of Weikl *et al.* is identified as a catheter throughout the reference, and, while it may have a guiding function, it is not

the procedure which is configured for percutaneous introduction and advancement within the patient's vasculature. If there is no teaching of advancing the device of Gant into the patient's body lumen, there surely can be no suggestion of percutaneously introducing and advancing the catheter (28) of Gants into the patient's arteries particularly the coronary arteries and cardiac veins of a human patient. Claims 30 and 35 also require the proximal guidewire port to be at least 10 cm from the distal end of the catheter shaft. The catheter of Gants is silent as to the distance of the proximal port from the distal end of the catheter and therefore cannot meet this requirement. Claims 30 and 32 also call for a guidewire with a core member and a coil on a distal portion of the guidewire. The catheter of Gants is just that, a catheter. It is not a guidewire and it does not have a core member and a coil. Thus, the teachings of Gants neither anticipate nor render obvious the presently claimed invention.

Applicant submits that the presently pending claims of this application define patentable subject matter and respectfully requests entry

of the above amendments and reconsideration and an early allowance of
these amended claims.

Respectfully submitted,

Edward J. Lynch

by George H. Cooper

Edward J. Lynch
Attorney for Applicant
Registration No. 24,422

Reg No 28281

CROSBY, HEAFEY, ROACH & MAY

1999 Harrison Street
P.O. Box 2084
Oakland, CA 94604-2084

Telephone: (510) 466-6805
Facsimile: (510) 273-8866

EJL:mk